For the Northern District of California

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

VNUS MEDICAL TECHNOLOGIES, INC.

No. C-05-2972 MMC

Plaintiff

٧.

DIOMED HOLDINGS, INC., DIOMED, INC., ANGIODYNAMICS, INC., and VASCULAR SOLUTIONS, INC.,

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION FOR SUMMARY JUDGMENT OF NO WILLFUL INFRINGEMENT

Defendants

Before the Court is defendants AngioDynamics, Inc. ("AngioDynamics"), Vascular Solutions, Inc., ("VSI"), Diomed Holding, Inc., and Diomed, Inc.'s (collectively, "Diomed") "Motion for Summary Judgment of No Willful Infringement," filed October 1, 2007. Plaintiff VNUS Medical Technologies, Inc. ("VNUS") has filed opposition, to which defendants have replied. Having considered the papers filed in support of and in opposition to the motion, the Court rules as follows.

To establish willful infringement, a patentee must prove "the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent" and such objective risk "was either known or so obvious that it should have been known to the accused infringer." See In re Seagate Tech., LLC, 497 F. 3d 1360, 1371 (Fed. Cir. 2007).

Defendants argue VNUS lacks evidence to establish the existence of an "objectively

high likelihood" that any defendant's actions constituted infringement. In opposition, VNUS argues it can establish its claim of willfulness, in light of evidence VNUS asserts would support a finding that each defendant, with knowledge of VNUS's patents, copied the methods set forth in VNUS's patents.

A. AngioDynamics

The evidence cited by VNUS pertaining to its assertion that AngioDynamics copied the patented methods is the following: (1) biolitec, Inc.'s ("biolitec") representation to the FDA, in a Form 510(k) prepared on November 7, 2001,¹ that biolitec's product "has the same intended use and indications for use as VNUS Medical Technologies' VNUS Closure System," (see Nguyen Decl., filed October 12, 2007, Ex. 12 at ANGV007352); and (2) deposition testimony offered herein by Russell Samson, M.D. ("Dr. Samson"), an expert retained by AngioDynamics. Specifically, when Dr. Samson was asked the question "Sitting here today, do you know whether the use of tumescent anesthesia occurred first in the VNUS RF procedure or with respect to the laser procedure?," (see id. Ex. 11 at 116:4-7), he responded: "My recollection is that the VNUS procedure predated laser ablation. It started out as what was called closure, where the attempt was to restore valvular function, rather than obliteration and destruction of the vein." (See id. Ex. 11 at 116:22-117:2.)

The basis for VNUS's copying claim is, as defendants state in their reply, "less than completely clear," (see Defs.' Reply, filed October 18, 2007, at 4:1), at least as it pertains to AngioDynamics. VNUS fails to explain how a statement of a non-party made to the FDA and/or an opinion offered at a deposition by a retained expert could support a finding that AngioDynamics, when it sold its products, "acted despite an objectively high likelihood that its actions constituted infringement of a valid patent," and that such objective risk "was either known or so obvious that it should have been known" to AngioDynamics. See

¹"510(k) notifications are submittals of engineering and clinical information which are provided to the FDA to permit that agency to assess the safety and effectiveness of a new product with regard to a predicate product which is already on the market." <u>CardioVention, Inc. v. Medtronic, Inc.</u>, 483 F. Supp. 2d 830, 840 (D. Minn. 2007) (internal quotation and citation omitted).

<u>Seagate</u>, 497 F. 3d at 1371. The above-referenced statements on which VNUS relies cannot be reasonably interpreted by a trier of fact as an admission that AngioDynamics "copied" the patented claims, or to otherwise support a finding of copying by AngioDynamics. The statement by biolitec in its Form 501(k) cannot be understood as a representation pertaining to the patented claims.² Additionally, the above-referenced testimony by AngioDynamic's expert does not make reference to AngioDynamics, let alone suggest AngioDynamics copied the claimed methods, and VNUS has not explained how Dr. Samson's testimony could implicitly be so understood.

Accordingly, AngioDynamics is entitled to summary judgment on VNUS's claim of infringement.

B. VSI

The evidence cited by VNUS pertaining to its assertion that VSI copied the patented methods is the following: (1) VSI's February 28, 2003 representation to the FDA that VSI's product is "similar, in design, function and intended use" to products marketed by Diomed and by AngioDynamics, (see Nguyen Decl. Ex. 7 at VS002533); (2) the above-quoted deposition testimony by Dr. Samson, who has been retained as an expert by VSI in the instant case; and (3) deposition testimony offered herein by VSI's Chief Executive Officer, Howard Root ("Root"). Specifically, when Root was asked the question "When was the first time that you were introduced to the concept of tumescent anesthesia?," (see id. Ex. 29 at 103:10-11), he responded: "Probably taking a look at the venous RF procedure in around the time of 2002." (See id. Ex. 29 at 103:12-13.)

The Court finds such evidence is insufficient to support a finding that VSI willfully

²Further, as defendants point out, the Court, at the Pretrial Conference conducted October 16, 2007, granted defendants' motion in limine with respect to statements made by defendants in a Form 501(k). Specifically, the Court precluded VNUS from referring to any such statement without first obtaining prior leave to court, such leave to be considered in the event VNUS is able to lay a foundation to show that a defendant who made a statement to the FDA had read the instructions for use included with VNUS's product, which instructions reference one of the VNUS patents at issue herein. VNUS has not, in opposition to the instant motion or otherwise, offered any evidence to support a finding that biolitec or AngioDynamics had read VNUS's instructions for use prior to biolitec's representation to the FDA.

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infringed the claims. VSI's statement to the FDA made no reference to VNUS's products, let alone any VNUS patent. Further, VNUS's reliance on the deposition testimony of Dr. Samson is unavailing for the reasons discussed above with respect to AngioDynamics. Finally, the above-quoted deposition testimony by Root does not give rise to a reasonable inference that VSI copied VNUS's claimed methods.

Accordingly, VSI is entitled to summary judgment on VNUS's claim of infringement.

C. Diomed

With respect to its assertion that Diomed copied the patented claims, VNUS relies on testimony offered by two of the inventors of a patented method owned by Diomed. First, VNUS cites Luis Navarro, M.D.'s ("Dr. Navarro") testimony given in a prior action Diomed filed against AngioDynamics and VSI, specifically, Dr. Navarro's testimony that the "use of [the] tumescent anesthesia technique to collapse the vein" was not his idea, but, rather, that he got the idea from hearing a "presentation" by VNUS consultants "Dr. Goldman" and "Dr. Weiss," in which "they were using it [tumescent anesthesia] as the primary way of achieving contact." (See id. Ex. 15 at 82:25-83:13.) Second, VNUS relies on testimony, also offered in the prior action filed by Diomed, by Robert Min, M.D. ("Dr. Min"), specifically, his testimony that the Diomed patent does not disclose the use of tumescent anesthesia for compression. (See id. Ex. 15 at 209:1-17.) Third, VNUS relies on deposition testimony provided by Dr. Navarro herein; specifically, when Dr. Navarro was asked the question "So it was after you filed your patent application that you appreciated the fact that tumescent anesthesia had the property of compressing the vein?," he responded: "[T]o use it in that particular situation and to take advantage, full advantage of it, yes." (See id. Ex. 30 at 30:6-15.) VNUS argues that in light of the above evidence, a trier of fact could reasonably find that Dr. Navarro and Dr. Min "copied" the idea of using tumescent anesthesia to compress veins from VNUS.3

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³Defendants argue the cited excerpts from Dr. Navarro and Dr. Min's testimony are properly understood as statements that they learned the use of tumescent anesthesia would allow an energy application device to make contact with a vein wall, not that they learned tumescent anesthesia could be used for compression purposes. On a motion for

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As defendants point out, VNUS has not offered any evidence that either Dr. Navarro or Dr. Min had knowledge of VNUS's patents at the time of VNUS's presentation on the use of tumescent anesthesia. As a result, VNUS has failed to show that, at the time of its inception, any "copying" by Dr. Navarro or Dr. Min constituted willful infringement. VNUS has offered evidence, however, that Diomed had actual knowledge of VNUS's '084 Patent by January 20, 2004, at the latest. 4 and of the '803 Patent by July 6, 2004. (See id. Ex. 17 at 2-3.) Consequently, a trier of fact could reasonably find that Diomed, as of those dates, had obtained actual knowledge that VNUS's patented methods included the step of "injecting a tumescent fluid solution . . . to cause the tissue to become tumescent and compress the hollow anatomical structure at the treatment site to a compressed size," see '084 Patent, col. 17, Il. 63-67), and that Diomed's sales thereafter constituted willful infringement. See Imonex Services, Inc. v. W.H. Munzprufer Dietmar Trenner GmbH, 408 F. 3d 1374, 1377 (Fed. Cir. 2005) (holding finding of willful infringement "hinges on when the defendants had actual knowledge of [the patentee's] patent rights, and their actions after that time") (emphasis added).

Defendants dispute that a trier of fact could so find, in light of Diomed's asserted reliance on the opinions of its counsel that such activities would not infringe. Neither of the two opinions on which defendants rely, however, is sufficient to foreclose a finding of willful

summary judgment, however, the evidence is construed in the light most favorable to VNUS, the non-moving party.

⁴VNUS argues it can establish Diomed knew of the '084 Patent as early as January 22, 2002, in light of Diomed's January 22, 2002 representation to the FDA that the "intended use, method of tissue interaction, specifications, clinical technique and clinical results of the Diomed [products] are the same or very similar to those of the [VNUS Closure System]." (See id. Ex. 3 at VS021174-75). As the Court stated at the October 16, 2007 Pretrial Conference, however, VNUS must lay a foundation to show that Diomed reviewed the instructions for use found in VNUS's Closure System product. To date, VNUS has not made such a showing. <u>See Imonex Services, Inc. v. W.H. Munzprufer Dietmar Trenner GmbH</u>, 408 F. 3d 1374, 1377 (Fed. Cir. 2005) (holding actual notice of patent, for purposes of claim of willful infringement, is not established by "constructive notice, as by marking a product with a patent number").

infringement.5

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In that regard, defendants first rely on a February 13, 2004 email sent to Diomed by attorney Jason M. Honeyman ("Honeyman"), who stated "[e]xcept for the recitation of a catheter with a working end/energy application device, it appears that the method of treatment instructed by Diomed falls within the scope of this claim [claim 1 of the '084 Patent.]" (See Nguyen Decl. Ex. 23). Although such statement could be understood as an opinion that the Diomed method does not meet the claimed limitation of "introducing a catheter having a working end with an energy application device at the working end into the hollow anatomical structure," see '084 Patent, col. 17, II. 58-60, the email, on its face, states any such "assessment" is "preliminary," (see id.). Further, no legal analysis for such assessment is set forth in the email. Defendants fail to show that reliance by Diomed by a self-described "preliminary" assessment of infringement would, as a matter of law, foreclose a finding of willful infringement. See Amsted Industries v. Buckeye Steel Castings, 24 F. 3d 178, 182-83 (Fed. Cir. 1994) (affirming jury's finding defendant willfully infringed; finding jury entitled to reject defendant's argument that its infringement was not willful, where defendant's argument based on its reliance on "preliminary" opinion of counsel).

Second, defendants rely on an email sent to Diomed on September 22, 2004 by Honeyman, who stated, "We believe the [VNUS] patent claims should not be found to reach the intended use of the Diomed disposables." (See Steenburg Decl., filed October 10, 2007, Ex. I.) No factual or legal basis for such conclusion is set forth therein. Under such circumstances, defendants fail to show that any reliance by Diomed on Honeyman's

⁵Defendants also argue that because Diomed has raised what defendants characterize as "substantial defenses" in the instant case, no trier of fact could reasonably find willful infringement. In support of this argument, defendants point out that VNUS did not seek summary judgment on Diomed's claims of invalidity. Defendants, however, cite no authority that a plaintiff is, as a matter of law, foreclosed from establishing a claim of willful infringement if it does not seek summary judgment on each claim of invalidity or other defense raised by defendants.

⁶The version of Exhibit I that defendants have filed herein is redacted; the Court's characterization of the email pertains only to the portion of the email that has been filed.

assessment would, as a matter of law, foreclosure a finding of willful infringement. See SRI Int'l, Inc. v. Advanced Technology Laboratories, Inc., 127 F. 3d 1462, 1466 (Fed. Cir. 1997) (holding district court, as trier of fact, did not err in finding defendant willfully infringed, where defendant relied on "conclusory" opinion of counsel that was "lacking both legal and factual analysis").

Accordingly, Diomed is not entitled to summary judgment on VNUS's claim of willful infringement.

CONCLUSION

For the reasons stated above, defendants' motion for summary judgment on VNUS's claim of willful infringement is hereby GRANTED in part and DENIED in part, as follows:

- 1. To the extent the motion seeks summary judgment on VNUS's claim of willful infringement against AngioDynamics and VSI, the motion is GRANTED.
- 2. To the extent the motion seeks summary judgment on VNUS's claim of willful infringement against Diomed, the motion is DENIED.

IT IS SO ORDERED.

Dated: October 24, 2007